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(54) Wound dressing.

(57) An occlusive wound dressing comprising a flexible closed cell polyurethane foam containing from about 5% to about 50% by weight of the foam of one or more water dispersible, water swellable, and/or water absorbing agents. A pressure sensitive adhesive is applied or laminated to one surface of the foam in a continuous layer or discontinuous pattern. A polymeric film or skin is laminated or formed on the opposite surface of the foam.

**EP 0 190 814 A2**

Richter et al. in U.S. Patent 3,566,871 disclose a hydrophilic polyurethane sponge for medical use in which the sponge pores contain a surfactant coating. McRae et al. in U.S. Patent 3,978,855 disclose a polyurethane foam surgical dressing in which a surface of the foam is compressed and wherein the foam also contains a wetting agent. Lock in U.S. Patent 3,975,567 discloses a polyurethane foam surgical dressing in which one surface is rendered lyophilic by applying pressure and heat. Lazlo in European Patent Application 41,934 disclose a wound exudate absorbent product comprising a polyurethane foam having a water-insoluble hydrophilic polymer such as cross-linked dextran incorporated within a portion of the foam cells. Marsan in U.S. Patent 3,713,445 discloses an ostomy sealing ring consisting of an open cell polyurethane or polyethylene foam containing a gelatinous material such as karaya powder and glycerine. Various polyurethane foam dressings are disclosed by Robins in U.S. Patent 3,113,568, Bentov in U.S. Patent 3,157,178, Wheeler in U. S. Patent 3,648,692, and Nowakowski in U.S. Patent 3,949,742.

surface of foam layer 12 or 12'. The adhesive 14 is applied as a discontinuous pattern on the surface of the foam so that portions of the foam surface remain uncovered. Preferably, the adhesive 5 14 is applied in the form of strips which may extend horizontally, vertically, or diagonally across the surface of the foam. Alternatively, adhesive 14 may be applied as a pattern of dots or squares across the surface of the foam. Adhesive 10 14 preferably covers from about 25% to about 75% most preferably about 65%, of the surface area of foam layer 12. In use, the wound dressing is applied to the body by pressing so that adhesive layer 14 contacts the wound site and surrounding 15 skin. The discontinuous pattern of pressure sensitive adhesive 14 permits the wound dressing to be firmly adhered to the body but enables the wound exudate to contact the foam wherein it reacts with the water dispersible, water swellable, and/or 20 water absorbing agents within the foam network.

The pressure sensitive microporous adhesive layer 14' is coated or laminated to one surface of foam layer 12' as a continuous layer so that the entire surface of the foam is covered. The 25 porosity of adhesive layer 14' enables wound exudate to migrate through this layer to contact the foam where it reacts with the water dispersible, water swellable, and/or water absorbing agents within the foam network.

30 The top surface of foam layer 12 or 12' when viewing the dressing placed on a wound is sealed so that soil and water can not penetrate into the dressing. A thin film 16 or 16' of polymeric material such as polyurethane can be laminated to 35 the top surface of foam layer 12 or 12' or the top

to about 50% by weight of the foam and particularly an equal weight equal weight blend of pectin, gelatin, and sodium carboxymethylcellulose together at about 30% by weight of the foam. A water insoluble starch-acrylonitrile graft co-polymer at from about 5% to about 22% by weight of the foam and most preferably at about 12% by weight of the foam. A mixture of from about 2 parts by weight of one or more of pectin, gelatin, and sodium carboxymethylcellulose, most preferably an equal weight blend of pectin, gelatin and sodium carboxymethylcellulose, and about one part by weight of a water insoluble starch-acrylonitrile graft copolymer. This mixture is present at from about 12% to about 48% by weight of the foam with the most preferred mixture being about 5% pectin, about 5% gelatin, about 5% sodium carboxymethylcellulose, and about 7.5% of a water insoluble starch-acrylonitrile graft copolymer by weight of the foam.

In addition, small amounts, i.e., in toto less than about 5% by weight of the foam layer, of other agents may be included with the water dispersible, water swellable and/or water absorbing agents. For example, a pharmaceutically active ingredient such as an antibiotic or antimicrobial agent, an antiseptic agent such as povidone iodine, or an antiinflammatory agent such as hydrocortisone or triamcinolone acetonide may be included. Other materials such as a deodorant, perfume agent, or antioxidant could be included. Also, substances conventionally employed in the manufacture of polyurethane foams to increase strength or flexibility can be included as long as they are safe and non-irritating to the human skin.

raising of the reaction temperature. Also, water may be used as a blowing agent since the isocyanate when reacted with water release carbon dioxide.

Typical polyurethane foam processes are  
5 described in more detail in Kirk-Othmer, Enc. of  
Chem. Tech., 3rd, (1979), Vol. 11, p 87 - 89 and  
Vol. 23, p 576 - 608, British Patents 1,550,614 and  
1,538,809 noted above, and in U.S. Patents  
3,004,934, 3,075,930, 3,441,523, 3,586,648,  
10 3,753,933, 4,156,759, 4,197,372, 4,327,195, and  
4,374,208.

In the preferred process the polyurethane  
foam 12 or 12' containing the water dispersible,  
water swellable, and/or water absorbing agents and  
15 any other optional agents is cast onto a polymeric  
film 16 or 16' which had previously been cast on  
silicone coated release paper. Alternatively, one  
surface of the foam 12 or 12' can be treated with  
heat and pressure to form skin 16 or 16'.

20 Pressure sensitive adhesive 14 may be of an  
acrylic based type for example a copolymer of  
isooctyl acrylate and acrylic acid as described by  
Ulrich in U.S. Patent RE 24,906 or a microporous  
acrylic adhesive as described by Copeland in U.S.  
25 Patent 3,121,021. Alternatively, pressure  
sensitive adhesive 14 may be a mixture of a rubbery  
elastomer preferably a mixture of low and medium  
molecular weight polyisobutylenes, one or more  
water dispersable agents preferably sodium  
30 carboxymethylcellulose and gelatin, a tackifier  
preferably a terpene resin, and a plasticizer  
preferably mineral oil as taught by Chen in U.S.  
Patent 3,972,328 or such a pressure sensitive  
adhesive in a microporous form as taught by Cilento  
35 et al in U.S. Patent 4,427,737.

ingredients. As taught by Cilento et al., in U.S. Patent 4,427,737, this microporous adhesive preferably contains of from about 35% to about 50% by weight of rubbery elastomer, from about 30% to about 60% by weight of water dispersible agents, and up to 35% by weight of one or more tackifiers, plasticizers, antioxidants and preservatives. Preferably, the elastomer is a mixture of low and medium molecular weight polyisobutylenes, the water dispersible agent is a mixture of a sodium carboxymethylcellulose and gelatin, the tackifier is a terpene resin, and the plasticizer is mineral oil.

The acrylic or rubbery elastomer adhesive can be made microporous by employing the solvent evaporation technique described by Copeland in 3,121,021 and Cilento et al. in 4,427,737. In this procedure, the solids are dispersed in a solvent such as heptane to form a slurry. The slurry is cast onto silicone coated release paper to the desired thickness and the material is then passed through a multi-zone drying tunnel so as to evaporate off the solvent.

Alternatively, the adhesive can be made microporous by forming an aqueous emulsion of the solids, adding a surfactant or a viscosity building agent such as sodium carboxymethylcellulose and incorporating air or other gaseous bubbles into the emulsion. This emulsion is then cast onto silicone coated release paper and dried by passing through a multi-zone drying tunnel.

The pressure sensitive microporous adhesive layer including the silicone coated release paper is laminated (adhesive 14' contacting the foam) with pressure to the surface of foam 12' opposite

Example 1

Polyurethane is cast onto a sheet of silicone release paper to give a film of about 1 mils thickness.

5 A flexible closed cell polyurethane foam is prepared by reacting appropriate amounts of a polyether polyol such as poly(oxyethylene) glycol, an isocyanate such as 4,4'-methylenebis(phenyl isocyanate), catalysts such as stannous octoate and dimethylaminoethyl ether and water (blowing  
10 agent) with sufficient starch-acrylonitrile graft copolymer (J-500 Water Lock). The starch-acrylonitrile graft copolymer is dispersed in the polyol. The other ingredients are mixed in a suitable vessel. The two mixtures are then intermixed at high speed  
15 in an in-line mixer, poured onto the polyurethane film, and allowed to cure to give a flexible closed cell polyurethane foam of about 25 mils thickness containing about 12% starch-acrylonitrile graft copolymer by weight of the foam.

20 An acrylic pressure sensitive adhesive such as a copolymer of isooctyl acrylate and acrylic acid in a 94:6 ratio is dispersed in an organic solvent. A portion of this slurry is poured onto a sheet of silicone coated release paper in horizontal strips  
25 of about 0.075 inch with about 0.05 inches between strips to leave a series of adhesive layers of about 2 mils thickness.

This series of adhesive layers is laminated to the closed cell polyurethane foam by gently  
30 compressing the adhesive to the foam by passing through pressure rollers.

The resulting wound dressing is cut to the desired size and packaged.

Example

		<u>6</u>	<u>7</u>	<u>8</u>	<u>9</u>	<u>10</u>
5	Guar gum	-	10	-	10	-
	Locust bean gum	-	-	-	-	-
	Pectin	-	-	-	-	10
	Karaya	-	-	-	-	-
	Gelatin	-	10	-	-	-
10	Sodium carboxymethylcellulose	10	-	-	-	10
	Collagen	10	-	-	-	-
	Cross-linked sodium carboxy- methylcellulose (Aqualon R)	-	15	-	10	-
	Starch-acrylonitrile graft	-	-	15	20	-
15	copolymer (J-500 Water Lock)	-	-	-	-	-
	Cross-linked dextran (Sephadex CM-C50)	-	-	-	-	10



Example 16

Following the procedure of Example 1 but substituting for the acrylic adhesive a pressure sensitive adhesive of the following composition:

5	<u>Percent by weight</u>	
•	Polyisobutylene (Vistanex LM-MH)	18.0
10	Polyisobutylene (Vistanex L-100)	20.0
	Terpene resin (Piccolyte)	20.0
	Butylated hydroxytoluene	0.5
	Mineral oil	8.5
15	Sodium carboxymethylcellulose	18.0
	Gelatin	15.0

A mixture of 0.31 kg. of polyisobutylene (Vistanex L-100), 0.28 kg. of sodium carboxymethylcellulose, and 0.23 kg. of gelatin is kneaded.

- 20 This mixture is added to a solution of heptane containing 0.28 kg. of polyisobutylene (Vistanex LM-MH), 0.31 kg. of piccolyte resin, 8 g. of butylated hydroxytoluene, and 0.13 kg. of mineral oil to form an adhesive slurry. A portion of this
- 25 slurry is poured onto a sheet of silicone release paper in horizontal strips of about 0.075 inch with about 0.05 inches between strips to leave a series of adhesive layers of about 4 mils thickness.

nitrile graft copolymer is dispersed in the polyol. The other ingredients are mixed in a suitable vessel. The two mixtures are then intermixed at high speed in an in-line mixer, poured onto the polyurethane film, and allowed to cure to give a flexible closed cell polyurethane foam of about 25 mils thickness containing about 12% starch-acrylonitrile graft copolymer by weight of the foam.

10 An acrylic pressure sensitive microporous adhesive is prepared by homogenizing an aqueous emulsion (52% by weight solids) of 100 g. of Gelva RA2333 (water-based pressure sensitive acrylic resin from Monsanto), adding 0.7 g. of sodium carboxymethylcellulose, and continuing the  
15 homogenation to introduce air bubbles into the emulsion. This slurry is cast onto a sheet of silicone coated release paper at a wet thickness of about 10 mils. This material is passed through a multi-zone drying tunnel with a residence time  
20 of 5 to 10 minutes. The resulting dry microporous adhesive is about 4 mils thick.

This microporous acrylic adhesive is laminated to the closed cell polyurethane foam by gently compressing the adhesive to the foam by  
25 passing through pressure rollers.

The resulting wound dressing is cut to the desired size and packaged.

Example

		<u>22</u>	<u>23</u>	<u>24</u>	<u>25</u>	<u>26</u>
5	Guar gum	-	10	-	10	-
	Locust bean gum	-	-	-	-	-
	Pectin	-	-	-	-	10
	Karaya	-	-	-	-	-
	Gelatin	-	10	-	-	-
10	Sodium carboxymethylcellulose	10	-	-	-	10
	Collagen	10	-	-	-	-
	Cross-linked sodium carboxy- methylcellulose (Aqualon R)	-	15	-	10	-
	Starch-acrylonitrile graft	-	-	15	20	-
15	copolymer (J-500 Water Lock)	-	-	-	-	-
	Cross-linked dextran (Sephadex CM-C50)	-	-	-	-	10

Example 32

Following the procedure of Example 17 but substituting for the microporous acrylic adhesive a pressure sensitive adhesive of the following

5 composition:

Percent by weight

	Polyisobutylene (Vistanex LM-MH)	18.0
10	Polyisobutylene (Vistanex L-100)	20.0
	Terpene resin (Piccolyte)	20.0
	Butylated hydroxytoluene	0.5
15	Mineral oil	8.5
	Sodium carboxymethylcellulose	18.0
	Gelatin	15.0

The above solids are dispersed in sufficient  
20 heptane to make a slurry containing 40% by weight  
solids. The slurry is applied via a knife-over-  
roller onto silicone coated release paper to a wet  
thickness of 10 mils. The material is then passed  
through a multi-zone oven with a residence time of  
25 5-10 minutes so as to reduce the solvent content  
to less than 1%. The resulting dry adhesive layer  
is 3 mils thick and has a porosity of about  
5cc/sec/in<sup>2</sup>. As the dry film emerges from the  
oven, it is laminated to the closed cell  
30 polyurethane foam prepared as described in  
Example 1 by gently compressing the adhesive

CLAIMS

1. An occlusive wound dressing comprising a flexible closed cell polyurethane foam having distributed therein from about 5% to about 50% by weight of said foam of one or more water dispersible, water swellable and/or water absorbing agents, a thin polymeric film or a skin laminated to one surface of said foam, and a pressure sensitive adhesive laminated to the other surface of said foam.
2. A wound dressing according to Claim 1 wherein the pressure sensitive adhesive is laminated to the surface of said foam in a discontinuous pattern.
3. The dressing of Claim 2 wherein said discontinuous pattern of pressure sensitive adhesive covers from about 25% to about 75% of the surface of the foam.
4. The dressing of Claim 1 wherein said water dispersible, water swellable, and/or water absorbing agents are one or more selected from the group consisting of sodium carboxymethylcellulose, calcium carboxymethylcellulose, pectin, gelatin, guar gum, locust bean gum, collagen, karaya, water insoluble cross-linked sodium carboxymethylcellulose, substantially water insoluble starch-acrylonitrile graft copolymer, and substantially water insoluble cross-linked dextran.
5. The dressing of Claim 4 wherein said foam is from about 10 to about 100 mils in thickness, said polymeric film or skin is from about 0.5 to about 3 mils in thickness, and said pressure sensitive adhesive is from about 1 to about 10 mils in thickness.

11. The dressing of Claim 10 wherein said pectin, gelatin, and sodium carboxymethylcellulose are present in said foam at about equal amounts on a weight percent basis.

12. The dressing of Claim 11 wherein said foam contains about 30% by weight of said mixture of pectin, gelatin, and sodium carboxymethylcellulose.

13. The dressing of Claim 12 wherein said pressure sensitive adhesive is an acrylic adhesive.

14. The dressing of Claim 12 wherein said pressure sensitive adhesive is a blend of low and medium molecular weight polyisobutylenes, sodium carboxymethylcellulose, gelatin, terpene resin, and mineral oil.

15. The dressing of Claim 12 wherein said pressure sensitive adhesive is applied to said foam in a strip pattern and covers about 65% of the surface area of said foam.

16. An occlusive wound dressing consisting essentially of a flexible closed cell polyurethane foam of from about 10 to about 100 mils thickness and a density of from about 10 pounds/cubic foot to about 50 pounds/cubic foot having distributed therein from about 5% to about 22% by weight of said foam of a water insoluble starch-acrylonitrile graft copolymer, a polyurethane film or skin of from about 0.5 to about 3 mils thickness laminated to one surface of said foam, and a pressure sensitive adhesive of from about 1

polyurethane film or skin of from about 0.5 to about 3 mils thickness laminated to one surface of said foam, and a pressure sensitive microporous adhesive of from about 1 to about 10 mils thickness laminated to the other surface of said foam in a discontinuous pattern covering from about 25% to about 75% the surface of said foam.

23. The dressing of Claim 22 wherein said foam is about 20 to about 30 mils thickness, said pressure sensitive microporous adhesive is from about 2 to about 4 mils thickness, and said polyurethane film or skin is about 1 mils thickness.

24. The dressing of Claim 23 wherein said foam contains about 5% by weight of pectin, about 5% by weight of gelatin, about 5% by weight of sodium carboxymethylcellulose, and about 7.5% by weight of a water insoluble starch-acrylonitrile graft copolymer.

25. The dressing of Claim 24 wherein said pressure sensitive adhesive is an acrylic adhesive.

26. The dressing of Claim 24 wherein said pressure sensitive adhesive is a blend of low and medium molecular weight polyisobutylenes, sodium carboxymethylcellulose, gelatin, terpene resin, and mineral oil.

32. The dressing of Claim 27 wherein said foam has a density of from about 10 pounds/cubic foot to about 50 pounds/cubic foot.

33. An occlusive wound dressing consisting essentially of a flexible closed cell polyurethane foam of from about 10 to about 100 mils thickness and a density of from about 10 pounds/cubic foot to about 50 pounds/cubic foot having distributed therein from about 10% to about 50% by weight of the foam of one or more agents selected from the group consisting of pectin, gelatin, and sodium carboxymethylcellulose, a polyurethane film or skin of from about 0.5 to about 3 mils thickness laminated to one surface of said foam, and a pressure sensitive microporous adhesive of from about 1 to about 10 mils thickness laminated to the other surface of said foam as a continuous layer.

34. The dressing of Claim 33 wherein said foam is from about 20 to about 30 mils thickness, said pressure sensitive microporous adhesive is from about 2 to about 4 mils thickness, and said polyurethane film or skin is about 1 mils thickness.



40. The dressing of Claim 39 wherein said foam is from about 20 to about 30 mils thickness, said pressure sensitive microporous adhesive is from about 2 to about 4 mils thickness, and said polyurethane film or skin is about 1 mils thickness.

41. The dressing of Claim 40 wherein said foam contains about 12% by weight of a water insoluble starch-acrylonitrile graft copolymer.

42. The dressing of Claim 41 wherein said pressure sensitive microporous adhesive is an acrylic adhesive.

43. The dressing of Claim 41 wherein said pressure sensitive microporous adhesive is a blend of low and medium molecular weight polyisobutylenes, sodium carboxymethylcellulose, gelatin, terpene resin, and mineral oil.

44. An occlusive wound dressing consisting essentially of a flexible closed cell polyurethane foam of from about 10 to about 100 mils thickness and a density of from about 10 pounds/cubic foot to about 50 pounds/cubic foot and having distributed therein from about 12% to about 48% by weight of said foam of a mixture of from about 2 parts by weight of one or more of pectin, gelatin, and sodium carboxymethylcellulose and about 1 part by weight of a water insoluble starch-acrylonitrile graft copolymer, a polyurethane film or skin of from about 0.5 to about 3 mils thickness laminated to one surface of said foam, and a pressure sensitive microporous adhesive of from about 1 to about 10 mils thickness laminated to the other surface of said foam as a continuous layer.

1/2

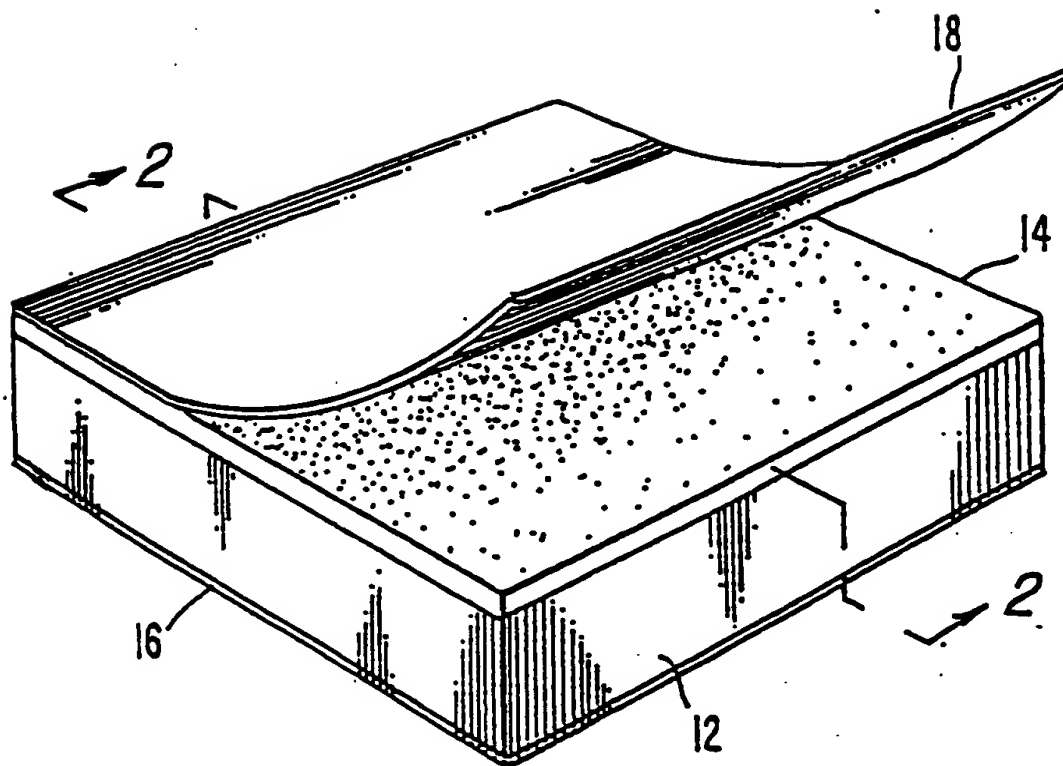


Fig. 1

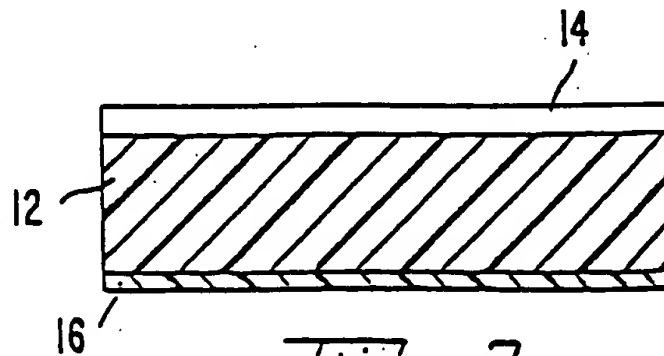


Fig. 2

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